

## CLAIMS

What is claimed is:

1. A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system of a subject, in a single, breath-activated step, comprising:
  - 5 administering particles comprising a bioactive agent, from a receptacle having a mass of particles, to a subject's respiratory tract, wherein:
    - i) the particles administered to the subject's respiratory tract have a tap density of less than  $0.4 \text{ g/cm}^3$ ;
    - 10 ii) at least 50% of the particles have a fine particle fraction less than  $4.0 \text{ }\mu\text{m}$ ; and
    - iii) at least about 50% of the mass of particles stored in the receptacle is delivered to the pulmonary system of the subject.
2. The method of Claim 1 wherein the particles have a tap density of less than  
15 about  $0.1 \text{ g/cm}^3$ .
3. The method of Claim 1 wherein the particles have a geometric diameter greater than about  $5 \text{ }\mu\text{m}$ .
4. The method of Claim 1 wherein the receptacle has a volume of at least about  $0.37 \text{ cm}^3$ .
- 20 5. The method of Claim 1 wherein the receptacle has a volume of at least about  $0.48 \text{ cm}^3$ .

6. The method of Claim 1 wherein the receptacle has a volume of at least about 0.67 cm<sup>3</sup>.
7. The method of Claim 1 wherein the receptacle has a volume of at least about 0.95 cm<sup>3</sup>.
- 5 8. The method of Claim 1 wherein delivery is primarily to the deep lung.
9. The method of Claim 1 wherein delivery is primarily to the central airways.
10. The method of Claim 1 wherein the bioactive agent is albuterol sulfate.
11. The method of Claim 1 wherein the bioactive agent is insulin.
- 10 12. The method of Claim 1 wherein the bioactive agent is growth hormone.
13. The method of Claim 1 wherein the bioactive agent is fluticasone.
14. The method of claim 1 wherein the bioactive agent is salmeterol.
15. The method of Claim 1 wherein the bioactive agent is a hydrophobic drug.
16. The method of Claim 1 wherein the bioactive agent is a hydrophilic drug.
- 15 17. The method of Claim 1 wherein the bioactive agent is a monoclonal antibody.
18. The method of Claim 1 wherein the particles are in the form of a dry powder.

19. The method of Claim 1 wherein administration to the respiratory tract is by a dry powder inhaler.
20. A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system of a subject, in a single breath, comprising:
- 5 administering dry powder particles comprising a bioactive agent, from a receptacle having a mass of particles, to a subject's respiratory tract in a single breath,
- wherein:
- 10 i) the particles have a tap density less than about  $0.4 \text{ g/cm}^3$ ;
- ii) at least about 5 milligrams of the bioactive agent is delivered to the pulmonary system of the subject.
21. The method of Claim 1 wherein said particles are spray dried particles.
22. The method of Claim 1 wherein at least 50% of the particles have a fine particle fraction less than  $4.0 \text{ }\mu\text{m}$ .
- 15 23. The method of Claim 1 wherein at least 75% of the particles have a fine particle fraction less than  $6.8 \text{ }\mu\text{m}$ .
24. The method of Claim 20 wherein at least 50% of the particles have a fine particle fraction less than  $4.0 \text{ }\mu\text{m}$ .
25. The method of Claim 20 wherein at least 75% of the particles have a fine
- 20 particle fraction less than  $6.8 \text{ }\mu\text{m}$ .

26. The method of Claim 20 wherein said particles are spray dried particles.
27. The method of Claim 20 wherein the particles deliver at least 10 milligrams of the bioactive agent.